JUN 2 6 2000

Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 978-749-1000
Telefax: 978-749-1599

Smith+Nephew

K001226

510(k) Summary
Smith + Nephew RF Arthroscopic Wand
Date Prepared:

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith + Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Mark Kieras
Regulatory Affairs Specialist

C. Device Name

Trade Name:	Smith + Nephew RF Arthroscopic Wand System
Common Name:	Electrosurgical cutting & coagulation probe
Classification Name:	Electrosurgical Probe

D. Predicate Devices

Mitek VAPR electrosurgery devices, K974022
ArthroCare ArthroWand electrosurgery devices, K971532

E. Description of Device

The proposed Smith + Nephew radio frequency (RF) arthroscopy wand system consists of three components:

1) a combined electrical connector, interconnecting cable, handle and wand (handle/wand portion),
2) an adapter module (composed of electrical connectors, microswitches, capacitor, isolation transformer, and interconnecting cables), and
3) a bending tool.

The RF device is a bipolar device designed to resect, ablate (debulk), excise, or coagulate bleeding blood vessels under a conductive fluid field (0.9% saline, Ringer's lactate, etc.). As such, a dispersive return pad is not required for operation of this device.

D. Intended Use

The Smith + Nephew RF Arthroscopic Wand is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels, and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, wrist, and hip

E. Comparison of Technological Characteristics

The Smith + Nephew RF Arthroscopic Wand is substantially equivalent in design, materials of contstruction, function and intended use to the following devices in commercial distribution: Mitek VAPR electrosurgery devices and ArthroCare ArthroWand Electrosurgery devices.

Mark Kieras
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2000

Mr. Mark Kieras
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K001226
Trade Name: RF Arthroscopic Wand System
Regulatory Class: II
Product Code: HRX
Dated: April 14, 2000
Received: April 17, 2000

Dear Mr. Kieras:

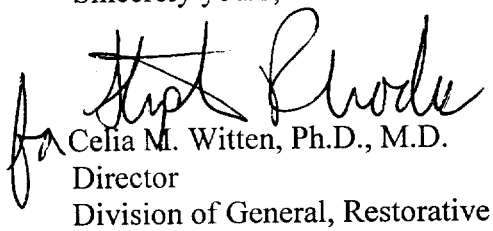
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K001226

Device Name : Smith + Nephew RF Arthroscopic Wand

Indications for Use :

The Smith + Nephew RF Arthroscopic Wand is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissue in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow, wrist, and hip

Additional information continued on second page.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001226

Nonrestrictive examples of arthroscopic surgery include:

Knee

- Meniscectomy
- Lateral Release
- Chondroplasty
- Synovectomy
- ACL Debridement
- Plica Removal
- Meniscal Cystectomy

Ankle

- Fracture Debridement
- Excision of Scar Tissue
- Synovectomy
- Chondroplasty

Wrist

- Synovectomy
- Cartilage Debridement
- Fracture Debridement

Shoulder

- Labral Tear Resection
- Synovectomy
- Excision of Scar Tissue
- Acromioplasty
- Bursectomy
- Subacromial Decompression
- Chondroplasty

Elbow

- Synovectomy
- Tendon Debridement
- Chondroplasty